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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,750	01/16/2001	Ichiro Azuma	0020-4802P	7730
2292	7590	02/13/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,750

Applicant(s)

AZUMA ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/19/01.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group IV, claims 21-25 filed on November 3, 2003 is acknowledged. Claims 1-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The use of the trademarks have been noted in this application. See page 16. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 21 is objected to for the recitation of "BCG-CWS" and "*Norcadia rubra*-CWS". The proper names should be recited at the first occurrence in the claims. For example, "BCG-CWS" should be "Bacillus Calmette-Guerin cell wall skeleton" and "*Norcadia rubra*-CWS" should be "*Norcadia rubra* cell wall skeleton". Correction is required.

4. Claim 25 is objected to for the following informalities: "havwherein" should be changed to "wherein" of other appropriate language. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21-25 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites "obtainable by". It is unclear as to what Applicant is referring? Clarification is required.
6. Claims 21 and 22 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 22 recite the "dispersion-aiding". It is unclear as to what Applicant is referring? Clarification is required.

The Examiner is viewing the claims as product-by-process claims. The claimed product (an oil-in-water emulsion) comprises a bacterial component and is encapsulated in an oil. Although the product claims contain method steps, the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 21 and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by Yamamura et al (*U.S. Patent Number 4,543, 253, published September 24, 1985*).

Claims 21 and 23-25 are drawn to an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin and a bacterial component is selected from BCG-CWS and *Nocardia rubra*-CWS is encapsulated in oil.

Yamamura et al teach compositions comprising *Nocardia rubra* cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis* (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as “wherein the emulsion is negative for agglutination reaction with lectin”, “having an particle diameter of about 100 μm or less is homogeneously dispersed” and “wherein the particle diameter is about 25 μm ” would be

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inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material

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structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 21 and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by Cantrell (*U.S. Patent Number 4, 877, 611, published October 31, 1989*).

Claims 21 and 23-25 are drawn to an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin and a bacterial component is selected from BCG-CWS and *Nocardia rubra*-CWS is encapsulated in oil.

Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* (column 4, lines 54-68) and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant) (column 7, lines 27-35). Cantrell teaches the formation of oil droplet emulsions (column 7, lines 35-40 and column 10). Claim limitations such as “wherein the emulsion is negative for agglutination reaction with lectin”, “having an particle diameter of about 100 μm or less is homogeneously dispersed” and “wherein the particle diameter is about 25 μm ” would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalene). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an

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unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Cantrell anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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9. Claims 21 and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by Yarkoni et al (*Infection and Immunity*, 28(3):881-886 (1980)).

Claims 21 and 23-25 are drawn to an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin and a bacterial component is selected from BCG-CWS and *Nocardia rubra*-CWS is encapsulated in oil.

Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as “wherein the emulsion is negative for agglutination reaction with lectin”, “having an particle diameter of about 100 μm or less is homogeneously dispersed” and “wherein the particle diameter is about 25 μm ” would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the

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increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

10. Claims 21-25 are rejected under 35 U.S.C. 102(e) as anticipated by Van Nest et al, (*U.S. Patent Number 6,451, 325 B1, published September 27, 2002*).

Claims 21-25 are drawn to an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin and a bacterial component is selected from BCG-CWS and *Nocardia rubra*-CWS is encapsulated in oil.

Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets (see the Abstract). Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria* (column 9,

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lines 8-15). Van Nest et al teach that the oils used in the composition include squalene (column 4, lines 45-48). Van Nest et al teach that emulsifying agents include in the composition include ethanol (column 10, lines 58-63). Claim limitations such as “wherein the emulsion is negative for agglutination reaction with lectin”, “having an particle diameter of about 100 μm or less is homogeneously dispersed” and “wherein the particle diameter is about 25 μm ” would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome

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the aspect of the product's purity is relied upon. Van Nest et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

11. No claims are allowed.

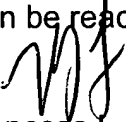
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Conclusion

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (572) 272-0857. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (572) 272-0864.


Vanessa L. Ford
Biotechnology Patent Examiner
January 30, 2004


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